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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,633	04/10/2006	Ozkan Yalkinoglu	Le A 36 293	3695
35969 7590 08/26/2009 Barbara A. Shimei Director, Patents & Licensing Bayer HealthCare LLC - Pharmaceuticals 555 White Plains Road, Third Floor Tarrytown, NY 10591				
EXAMINER BASS, DIRK R				
ART UNIT 1797		PAPER NUMBER		
MAIL DATE 08/26/2009		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/525,633

## Applicant(s)

YALKINOGLU ET AL.

## Examiner

DIRK BASS

## Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/5508)  
Paper No(s)/Mail Date 23 Feb 2005
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election with traverse of group I in the reply filed on 17 July 2009 is acknowledged. The traversal is on the ground(s) that the three groups of inventions recited in the restriction requirement dated 17 February 2009 all share a special technical feature, i.e. methods and kits for assessing the state of Alzheimer's disease based on the detection of one or more polypeptide biomarkers. This is not found persuasive because the special technical feature does not make a contribution over the applied prior art, thereby establishing a lack of unity among groups I-III.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 1-4** are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Landfield et al., USPA 2005/0071088 (Landfield).

Regarding claims 1-4, Landfield discloses a method of assessing a state of Alzheimer's disease (abstract and ¶ 0006) comprising detecting neurosecretory protein VGF (¶ 0114, claims 1,32).

Landfield does not explicitly disclose neurosecretory protein VGF having the molecular mass recited in claim 1 or the sequence as recited in claim 3, nevertheless, Landfield discloses the same preferred polypeptide as disclosed in applicant's claims; therefore, it is inherent that the neurosecretory protein VGF as disclosed in Landfield has a molecular mass of  $4824 \pm 20$  Da and an identical sequence to that of sequence ID No: 17 (see MPEP 2112).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 1-8 and 11-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Delacourte et al., USPA 2005/0175626 (Delacourte) in view of Landfield et al., USPA 2005/0071088 (Landfield).

Regarding claims 1-4 and 11-16, Delacourte discloses a method of assessing a state of Alzheimer's disease (see claim 1) comprising separating polypeptides from cerebral spinal fluid samples via antibodies specific for said polypeptides and detecting said polypeptides via SELDI-TOF MS (see Example 3, ¶ 0207-0210).

Delacourte fails to explicitly disclose a method wherein the polypeptide being detected is neurosecretory protein VGF.

Landfield discloses a method of assessing a state of Alzheimer's disease (abstract and ¶ 0006) comprising detecting neurosecretory protein VGF (¶ 0114, and claims 1, 32).

Landfield does not explicitly disclose neurosecretory protein VGF having the molecular mass recited in claim 1 or the sequence as recited in claim 3, nevertheless, Landfield discloses the same preferred polypeptide as disclosed in applicant's claims; therefore, it is inherent that the neurosecretory protein VGF as disclosed in Landfield has a molecular mass of  $4824 \pm 20$  Da and an identical sequence to that of sequence ID No: 17 (see MPEP 2112).

At the time of invention, it would have been obvious to one skilled in the art to use the neurosecretory protein VGF disclosed in Landfield in the method of Delacourte because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8/24/2009

/Yelena G. Gakh/  
Primary Examiner, Art Unit 1797

/DRB/  
Dirk R. Bass